K040117

APR 2 1 2004

Bob Symington

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510(k) SUMMARY

Name of device:	UNIPORT
Common name:	Mobile Dental Operative Unit
Classification name:	Dental Operative Unit Class I
Product code:	EIA
Predicate device:	A-dec PAC I Portable Unit 510(k) number K903451 Dental Operative Unit Class I

This device is intended to provide general restorative dental care to those who are unable to visit the dental office.

The UNIPORT has been designed to provide ease in set-up and transportation as well as good dental care. Reliable air supply being an utmost necessity, it has 9.8 L of air storage supplied by a 3/4 hp compressor to maintain pressure during daily practice. For ease in set-up, take-down, and transport, the UNIPORT is truly self-contained - all components are mounted in a lightweight unitized cabinet with wheels. The cabinet, a shell containing the operational components, is made of food grade polyethylene for durability; its smooth exterior is easy to wipe down and disinfect between operations. While the outside of the UNIPORT appears different to others, the actual operating components are similiar to those used in dental clinics around the nation.

It has, of course been a constant imperative in the design of the UNIPORT device to replicate the functions of a standard dental operative unit such as the predicate device. A comparison of the relative features of the UNIPORT device to the features of the predicate device confirms that this has been achieved.

UNIPORT Product Features:	PAC I Portable Unit Features:
Manual control for two handpieces	Manual control for two handpieces
Oil collection system	Oil collection system
Autoclavable syringe	Autoclavable syringe
Wet/dry foot control	Wet/dry foot control
Self-contained water bottle	Self-contained water system
3/4 hp 110 or 220 VAC compressor	$\frac{1}{2}$ hp 120 or 240 VAC compressor

UNIPORT Product Features:	PAC I Portable Unit Features:
9.8 liters of air storage	4 liters of air storage
Air filter/dryer	Air filter regulator with moisture separator
HV and saliva ejector vacuum with individual actuation	Air saliva ejector
One-piece molded plastic case 36-3/4" x 19-7/8" x 20-3/4"	Fixed-height mobile stand 33" x 21-$\frac{1}{2}$" x 21"
Power bar for accessories	Duplex electrical outlet

A comparison shows the UNIPORT to have the same features as the predicate device with a larger compressor and a greater air supply.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2004

Arrow Industries LLC
Mr. Robert Symington
530 5th Street
Neche, North Dakota 58265-4033

Re: K040117
Trade/Device Name: Uniport Self-Contained Portable Dental Unit
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: April 6, 2004
Received: April 12, 2004

Dear Mr. Symington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

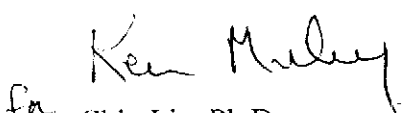
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040117

Device Name: UNIPORT self-contained portable dental unit

Indications for Use: This device is intended for delivery of general restorative dental care for those who cannot visit the dental office.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Beck DDS for Dr Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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